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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/048,063	SHIMONO ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,30,33,34,37 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,30,33,34,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 7/7/08

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 29, 30, 33, 34, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lerner et al (USPN 5,840,332 hereafter '332) in view of Dutkiewicz et al (USPN 6,197,322 hereafter '322). The claims are drawn to a process of making a solid product comprising a core, first layer comprising a water-insoluble polymer having chitosan dispersed therein, and an enteric coating, wherein the process comprising coating the core and evaporating the ethanol or water by drying.

4. The '332 patent discloses a solid formulation comprising a core and successive coatings (abstract). The coating composition comprises a water-insoluble carrier with a particulate dispersed therein (col. 9, lin. 38-65). The particulate matter is chitosan, and the water-insoluble

include well known such as various Eudragit polymers along with ethylcellulose (*Ibid.*). The form further comprises an enteric coating (claim 4). The enteric coating comprises well-known enteric polymers including those based on methacrylic acid and methyl methacrylate copolymer (claim 17). The dosage form comes as a tablet, or pill, or capsule (abstract), and is designed for colonic delivery (col. 6, lin. 57-65). The reference teaches method of producing the coatings including dispersing the solid particulates in the water-insoluble polymer and coating a core pellet (examples). Ethanol is used as a solvent for the coating layer and is driven off by drying (examples).

5. The reference differs from the claims in its exemplified particulate matter and the ratio at which the particles are present in the coating layer. The claims recite a range from 1:4-4:1, where the claims exemplify a radio from 1:1-3:7. However the 3:7 ratio is encompassed within the wider range of the claimed ratio. Further is remains the position that such modulations in ratio are merely an optimization of ranges. The process of the '332 patent provide sustained release (Figures) of a coated solid dosage from. Also the resulting products are within the same field of endeavor and solve the same problem. It remains the position of the Examiner that the general condition of the claims have been met by the '332 patent.

6. The reference also is silent to the specific particle size of the chitosan powder. Chitosan powder is a common ingredient in coating materials as is known in the art as seen in the '322 patent. The '322 patent discloses a chitosan coating suspension comprising chitosan particles ranging in size from 0.1-80 microns (col. 3, lin. 25-35). The powder suspension is applied to hydrophobic and/or hydrophilic polymers such as polyethylene and polyamides copolymers (col. 3, lin. 1-5). It would have been well within the level of skill in the art to apply the chitosan

suspension to the coating method of the '332 patent in order to provide a better surface area and more adhesion to the surface of the core.

7. With these things in mind it would have been obvious to combine the chitosan suspension of the '322 patent into the coating composition of the '332 in order to provide an even coating and improve the release of the active agent in the core. It would have been well within the level of skill in the art to make this combination with an expected result of a stable and useful controlled release composition.

Response to Amendment

The Declaration under 37 CFR 1.132 filed 7/7/08 is insufficient to overcome the rejection of claims 29, 30, 33, 34, 37 and 38 based upon USC 103(a) as set forth in the last Office action because: the Declaration is not commensurate in scope with the instant claims. The claims recite a process for producing a pharmaceutical formulation comprising coating a formulation with a solution comprising a polymer and chitosan powder in a ratio *from about 1:4 to about 4:1*. The prior art discloses a similar process where the ratio of chitosan powder is 1:1, 3:7 and 7:3. The declaration compares each of these points to distinct points within the range (4:1, 2:1, 1:1 1:2 and 1:4). However the claims recite that the range is from about 1:4 to about 4:1, meaning that all ratios in and around the range would be effective. The modifier about does not impose appreciable limitations on the range, as long as the functionality of the ratio remains the same in the prior art. The prior art discloses a sustained release formulation, as recited in the claims, as such the functionality of the chitosan and the polymer remain the same. Further of the points tested by the Declaration only represent 5 distinct points along the infinite points between *from about 1:4 to about 4:1*. Certainly 1:2.3 and 2.3:1 (3:7 and 7:3) fall within the range of the instant

claims, yet is not tested as their comparable ratios along with the discreet point of the Declaration. The claims are drawn to a broad range of ratios that is not commensurate in scope with that of the Declaration or the instant Specification. For these reasons the claims remain rejected.

Response to Arguments

Applicant's arguments filed 7/7/08 have been fully considered but they are not persuasive. Applicant argues that:

> The combination of the '332 and 322 patents do not obviate the instant claims since they do not have the same coating or control releasing functions.

It remains the position of the Examiner that the combination of the '332 and the '322 patents obviate the instant claims. First, as discussed above the Shimono Declarations while thorough are not commensurate in scope with the instant claims. The instant claims recite that range of chitosan to polymeric material broadly as *from about 1:4 to about 4:1*. As discussed above the modifiers about do not impart appreciable limitations on the ranges over the prior art as long as the functionality of the ranges remains the same. The ratio of chitosan to polymer material is a factor in imparting a sustained release profile to the dosage form. The formulation of the prior art combination also maintained a sustained release profile, thus maintaining the functionality of the chitson:polymer ratio. Along with be broad the range is al inclusive of every ratio from about 1:4 to about 4:1. This includes an infinite amount of ratios that are not exemplified in the instant specification or by the Declaration. Applicant argues that the Lerner patent is not a sustained released formulation, however as indicated by the Abstract and the Figures, the release of the drug can be controlled by various factors **including** the particulate

material in the coating (abstract). The drug release is controlled by the varying factors including the "(4) ratio of particulate matter" (col. 11, lin. 50-55). The '332 patent is however silent to the size of the chitosan particles. It remains the position of the Examiner that it would have been obvious to include a chitosan suspension such as described in the '322 patent since both patents disclose similar polymers and coating compositions.

Applicant argues that the chitosan of the '322 patent is fully dissolved in a solution and thus has no particle size. Applicant's attention is directed to (col. 3, lin. 25-37) where coating **suspensions** are discussed, where discreet chitosan particles are suspended in a dissolve polymer. These suspensions maintain the particles size of the chitosan from 0.1-80 microns. These disclosures establish that coating suspensions comprising particulate chitosan and polymeric materials are well known in the art. The chitosan suspension would have provides improved adhesion to the core material of the '332 patent. It would have been obvious to include the suspension under the suggestion of the '332 patent in order to improve the adhesion of the coating material to the core and to provide a sustained release of the core material.

Applicant argues that the patent combination is not within the same field of endeavor and does not solve the same problem. However as discussed above the claims recite a process for making a formulation, and the '332 patent discloses the same processing steps. The Lerner patent discloses that by manipulating certain parameters, any controlled release profile can be achieved. For the purposes of the invention sustained release profiles are exemplified (release over a 6 hour interval). These parameters include controlling the particulate material embedded in the coating material and its particle size. The '322 patent provides a specific coating material with improved adhesion properties. It would have been obvious to combine the teachings and

suggestions since both disclose the coating of a substrate with particulate chitosan. The Lerner patent discloses sustained release formulations comprising a core and a coating comprising the same polymers and particulate material as that of the instant claims. The '332 patent provides the particular particle size (a parameter discussed in the Lerner patent) and an improved adhesion property. The combination would result in a coated sustained release formulation where the coating adheres tot he core material longer providing a longer release rate. For these reasons the claims remain rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618